Case 2:10-cv-01990-MRP -RZ Document 125-1

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

- I, Michael N. Brant-Zawadzki, declare and state as follows:
 - I have been practicing medicine as a diagnostic radiologist for 35 years. 1.
 - I am currently the Executive Medical Directory of the Neurosciences 2. Institute at Hoag Memorial Hospital in Newport Beach, CA.
 - I have been board certified in Radiology since 1979 and Neuroradiology since 1995 (the first year board certification for Neuroradiology was offered).
 - I attended medical school at the University of Cincinnati College of 4. Medicine, where I graduated first in my class and was awarded the Stella F. Hoffheimer Award. After an internship in internal medicine at UC San Diego, I completed my residency in Diagnostic Radiology at Stanford University Medical Center. I also completed a 1-year fellowship in Neuroradiology at Stanford University Medical Center.
 - After my fellowship, in 1980, I obtained a full time academic post as an 5. Assistant Professor at UC San Francisco. During my first three years at UC San Francisco, I became involved with the Department of Radiology's imaging laboratory, where one of the first commercialized MRI instruments was being designed and developed. I became the neuroradiologist in charge of the development of clinical magnetic resonance imaging applications for the brain and the spinal region. I co-directed the MRI animal research laboratory at UC San Francisco's main academic hospital during this period as well. Our department generated a large number of original research articles, book chapters and books.
 - I have authored or co-authored over 180 peer reviewed articles in the medical literature, including some of the fundamental articles regarding MRI imaging of the central nervous system. I also wrote the first textbook on MRI imaging of the central nervous system ever published, and was a contributor to a

27

28

45

7 8

6

9

11

1213

1415

16

17

18

19

20

2122

23

24

25

2627

28

- large number of chapters and non-peer reviewed articles. I have also lectured throughout the world on the topic of MRI imaging of the central nervous system.
- 7. In recognition of my works, I was also awarded the Gold Medal from the Society of Magnetic Resonance in Medicine for my outstanding pioneering achievements in magnetic resonance imaging.
- 8. Claim element 3(d)[iii] of U.S. Patent No. 5,560,360 (the "360 patent") requires that "[the] characteristic spin-spin relaxation coefficient [of the nerve] is substantially longer than that of other surrounding tissue." '360 patent at 37:54-56 (emphasis added). A person of ordinary skill in the art understands that the "characteristic spin-spin relationship coefficient" of a tissue refers to the T2 decay time of the tissue. This claim language, therefore, reflects that the nerve must have a T2 decay time that is substantially longer than the tissue around it. Each structure shown on an MR image has its own characteristic T2 decay time. Although a structure's T2 decay time varies depending on the field strength, the T2 decay time is measurable for a given field strength. Attached hereto as Exhibit A is a true and correct copy of an article I coauthored entitled "Reproducibility of Relaxation Times and Spin Density Calculation from Routine MR Imaging Sequences: Clinical Study of the CNS," which lists the T2 decay times for various tissues at a field strength of 0.35 Tesla. The article was published in the American Journal of Neuroradiology in 1985.
- 9. For purpose of this declaration, I assume that the structure in Figure 5 of Hajnal et al., MR Imaging of Anisotropically Restricted Diffusion of Water in the Nervous System: Technical, Anatomic, and Pathologic Considerations in *Journal of Computer Assisted Tomography* 15(1):1-18 (Jan./Feb. 1991) ("Hajnal reference") is the trigeminal nerve, as represented by Hajnal et al. In Figure 5, the portion of the trigeminal nerve shown is located inside the skull and is therefore surrounded by cerebral spinal fluid ("CSF").

Russ, August & Kabat

10. The characteristic T2 decay time of the trigeminal nerve is not substantially
longer than that of surrounding tissue regardless of the magnetic field strength, as
required by claim element 3(d)[iii] of the '360 patent. For example, at a field
strength of 0.35 tesla, the T2 decay time for the surrounding cerebral spinal fluid
is 166.3 ms. At the same field strength, the T2 decay time of the trigeminal nerve
is similar to – not substantially longer than – surrounding white and grey brain
matter, which ranges from 56.8 ms to 59.8 ms. The only reason the surrounding
CSF appears black, and the nerve appears brighter, in Figure 5 is because Hajnal
et al. used diffusion weighted sequences, which make essentially pure water
collections like spinal fluid look black (diffusion weighted sequences are
designed to show increased signal from tissue where microscopic water motion is
restricted by membranes or other boundaries).

Therefore, in my opinion, Figure 5 of the Hajnal reference does not meet 11. the limitations of element 3(d)[iii] of the '360 patent.

I declare under penalty of perjury that the statements in this declaration are true and correct.

Signed on August 8, 2011 in Newport Beach, California.

By:

Michael N. Brant-Zawadzki, M.D., F.A.C.R